BMJ 1999;319:1133 (23 October) Letters

Association between type 1 diabetes and Hib vaccine

Causal relation is likely

We initiated and funded a collaborative study with Tuomilehto on the effect of the *Haemophilus influenzae* type b vaccine on type 1 diabetes and found that the data support a causal relation (paper submitted for publication). Furthermore, the potential risk of the vaccine exceeds the potential benefit. We compared a group that received four doses of the vaccine, a group that received one dose, and a group that was not vaccinated. The cumulative incidence of diabetes per 100 000 in the three groups receiving four, one, and no doses of the vaccine was 261, 237, and 207 at age 7 and 398, 376, and 340 at age 10 respectively.

Karvonen et al's analysis is not rational, and their conclusion is not supported by our data.[1] Their calculations of relative risk are also misleadingly low, and we urge readers to check them. Most researchers would compare the group who received four doses with the group that was not vaccinated or the two vaccinated groups with the group that was not vaccinated. The results of both comparisons reach significance. The cumulative difference in cases of type 1 diabetes per100 000 between those receiving four doses and those who were not vaccinated is 54 cases (P=0.013) at 7 years and 58 cases at 10 years (P=0.029; single tail Fisher test). The relative risk is 1.26 at 7 years. The cumulative difference between those receiving four doses or one dose of the vaccine and those who were not vaccinated is 42 cases (P=0.016) at 7 years and 47 cases at 10 years (P=0.028).

The rise in diabetes, just one potential adverse effect, exceeds the benefit of the vaccine, which has been estimated to prevent seven deaths and 7-26 cases of severe disability per 100 000 children immunised.[2] Even the difference in cases of diabetes between the groups receiving four doses and one dose exceeds the mean expected benefit. Temporal changes in the incidence of diabetes do not explain the differences since there were an extra 31 cases of type 1 diabetes per 100 000 children aged 5-10, and the incidence of diabetes in this group had been stable for about 10 years before this.[3] Furthermore, sharp rises in diabetes have been recorded in the United States[4] and the United Kingdom[5] after the introduction of the haemophilus vaccine.

Public health officials want to avoid scaring the public, but they risk depriving damaged children of compensation. Denials of safety issues may erode public confidence, especially since diabetes induced by the vaccine may be avoided by starting vaccination a few weeks earlier.

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[a] Competing interests: Methods used in the authors' research (including methods of testing vaccines for the induction of diabetes and methods of giving vaccines without inducing diabetes) are covered by patents owned by Classen Immunotherapies. Dr John Classen holds shares in Classen Immunotherapies; Dr David Classen owns no shares in the company, receives no funding from it, and has no financial ties to it or this research.

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